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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,564	11/30/2001	Andre Lieber	30429-2USWO	8863
26941	7590	10/02/2003	EXAMINER	
MANDEL & ADRIANO 55 SOUTH LAKE AVENUE SUITE 710 PASADENA, CA 91101			MARVICH, MARIA	
			ART UNIT	PAPER NUMBER
			1636	9
DATE MAILED: 10/02/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/980,564

Applicant(s)

LIEBER ET AL.

Examiner

Maria B Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 59-120 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 59-120 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***Election/Restrictions***

Claims 1-58 were canceled in a preliminary amendment filed 11/30/01, Paper No. 4, and new claims 59-120 are pending in the instant application and are subject to the following restriction requirement.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 59-62, 65-75 and 118-119 drawn to a first generation recombinant adenovirus a portion of which integrates into a host cell genome.

Group II, claims 63-64, 76-97 and 118-119 drawn to a first generation recombinant adenovirus which targets a host cell of interest and a portion that integrates into the host cell genome.

Group III, claims 98-109 and 118-120 drawn to a recombinant gutless adenovirus vector a portion of which integrates into a host cell genome.

Group IV, claims 110-114 drawn to a method of producing a resolved gutless adenovirus vector via homologous recombination between two adenoviral vectors.

Group V, claims 115-116 drawn to an adenovirus library comprising a plurality of adenovirus expressing fiber proteins displayed and modified by random peptide insertions.

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Group VI, claims 117, drawn to a screening method for targeting adenovirus vectors for gene therapy comprising contacting a plurality of cells with an adenovirus library with fiber proteins displayed and modified by random peptide insertions.

PCT Rule 13.2 requires that unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Group I-VI do not related to a single general inventive concept because they lack the same or corresponding technical feature. The “special technical feature” of Group I is a first generation recombinant adenovirus comprising a left inverted terminal repeat (ITR), a first inverted repeat (IR), a transgene, a second IR, an adenoviral sequence that directs replication and a right ITR, which is shown by Wilson et al. US 5,856,152 (see e.g. Figure 1A), to lack novelty of inventive step and does not make a contribution over the prior art.

MPEP 1875.01(d) states “If multiple products, processes of manufacture or uses are claimed, the first invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c).” As the special technical feature of Group I lacks novelty, the inventions of Group I-VI do not form a single general inventive concept and instead are composed of the following inventions. The technical feature of Groups II is drawn to a first generation recombinant adenovirus, which targets a host cell of interest and a portion that integrates into the host cell genome. The technical feature of group III is drawn to a recombinant gutless adenovirus vector a portion of which integrates into a host cell genome. The technical

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feature of Group IV is drawn to a method of producing a resolved gutless adenovirus vector via homologous recombination between two adenoviral vectors. The technical feature of Group V is drawn to an adenovirus library comprising a plurality of adenovirus expressing fiber proteins displayed and modified by random peptide insertions. The technical feature of Group VI drawn to a screening method for targeting adenovirus vectors for gene therapy comprising contacting a plurality of cells with an adenovirus library with fiber proteins displayed and modified by random peptide insertions.

Applicant is reminded that upon cancellation of claims to a non-elected inventions, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Zeta Adams, whose telephone number is (703) 305-3291.

Maria B Marvich, PhD  
Examiner  
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September 30, 2003

  
GERALD R. LEFFERS  
PRIMARY EXAMINER